REMARKS

Applicant wishes to thank the Examiner for the courtesy extended in conducting a phone interview held on July 30, 2007 to discuss the amendments to claim 1 as herewith submitted. Applicant acknowledges that the Examiner was unable to provide clear guidance as to whether the amendment to claim 1 would overcome the Examiner's outstanding rejections under Section 103(a), and that a further search may also be required before claim 1, as amended, can be allowed. Applicant thanks and acknowledges in advance the Examiner's time an efforts in scheduling a second interview on August 21, 2007 at 10 a.m. to further discuss the pending rejections in light of the recent Supreme Court ruling in *KSR*.

Claims 1-10 and 17-27 are pending in the present application. Claim 1 has been amended to overcome the Examiner's rejection under Section 103(a) by limiting the subject matter of that claim to "hG-CSF containing no sugar chain"..."wherein, when the 1st amino acid is replaced, the replaced amino acid is Ser." Support for this amendment to the Claim is found in the specification from page 4 paragraph 2 to page 7 paragraph 2. No new matter has been added.

The Examiner rejected Claims 1-8, 18, 19, 21-24, 26 and 27 under Section 103(a) as being unpatentable over Kuga et al in view of EP 0256843A1. Further, the Examiner rejected claims 9 and 10 as being unpatentable over Kuga et al. in view of EP 0256843A1 and further in view of Builder et al. Applicant respectfully traverse these grounds of rejection.

The present invention as defined in amended claim 1, is directed to a modified human granulocyte-colony stimulating factor(hG-CSF) containing no sugar chain, which is characterized in that at least one of the 1st, 2nd, 3rd and 17th amino acids of wild-type hG-CSF (SEQ ID NO: 2) is replaced by other amino acid(s) and has no terminal Met residue at the N-terminus thereof, wherein when the 1st amino acid is replaced, the first amino acid is Ser.

On page 4 of the Office Action, the Examiner states that "Kuga et al does not specifically teach a modified hG-CSF lacking an N-terminal methionine....however, Kuga et al acknowledges that the addition of the N-terminal methionine is disadvantageous and discloses enzymatic methods of removing the N-terminal methionine..., See col. 46, li. 29-40." Further, on page 5, paragraph 1 of the Office Action, the Examiner states that "Kuga et al does not teach use of the E. coli thermoresistant enterotoxin II signal peptide."

Applicant respectfully submits that Kuga does not teach how to produce a modified hG-CSF lacking an N-terminal methionine and instead emphasizes use of enzymatic cleavage. See col. 46, lines 37-40 of Kuga, wherein that reference reads "the use of the enzymatic cleavage technique according to the invention is advantageous since such products can be produced without addition of methionine to the N-terminus." Furthermore, the invention of the present application is a non-glycosylated hG-CSF, unlike the hG-CSF disclosed in Kuga. Accordingly, there is nothing in the teaching of Kuga to motivate one of ordinary skill in the art to obtain a modified hG-CSF as set forth in claim 1 lacking an N-terminal methionine.

In addition, one skilled in the art could not anticipate, predict or expect from the teaching of Kuga et al., even if combined with the use of the *E.coli* thermoresistant enterotoxin II as disclosed in Builder et al., that a modified hG-CSF (especially, [Ser17] hG-CSF) can be successfully produced from prokaryotic transformants without a Met residue when an appropriate secretory signal peptide is employed in preparation of its expression vector. To suggest otherwise constitutes using hindsight to combine the references based upon what applicant teaches. This is contrary to 35 USC 103, contrary to the recent Supreme Court ruling in KSR, and contrary to common sense. Although KSR permits the consideration of motivation from outside the teaching of the reference, the application of hindsight is still prohibited.

Moreover, Applicant is not aware of any external sources or references that would motivate one of ordinary skill in the art to combine the teachings of Kuga with either EP 0256843A1 or Builder et al., unless hindsight is used based upon the teaching in the subject invention.

For all of the above reasons, no basis exists to support a rejection over Kuga et al taken alone or in combination with EP 0256843A1 and Builder et al based upon obviousness under 35 USC 103 .

Reconsideration and allowance of claims 1-10 and 17-27 is respectfully solicited.

Respectfully submitted
Attorney for Applicant,

By: _____
Eugene Lieberstein
Registration No. 24,645

Dated: August 16, 2007

CUSTOMER NO. 01109

ANDERSON KILL & OLICK, P.C.
1251 Avenue of the Americas
New York, New York 10020-1182
(212) 278-1000

CERTIFICATE OF EFS-WEB TRANSMISSION

I hereby certify that this Amendment is being submitted via EFS-Web and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on August 17, 2007.

_____
Audrey de Souza